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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/749,346

12/30/2003

Daniel F. Justin

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08/13/2008

WORKMAN NYDEGGER
60 EAST SOUTH TEMPLE
1000 EAGLE GATE TOWER
SALT LAKE CITY, UT 84111

EXAMINER

STEWART, ALVIN J

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/749,346	Applicant(s) JUSTIN ET AL.	
	Examiner Alvin J. Stewart	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 18, 21, 23, 24, 26-28, 30, 31, 38-40, 42, 43, 45, 47, 50, 55, 56 and 58-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14, 18, 21, 23, 24, 38-40, 42, 43, 45, 47, 50, 59-62, 66 and 67 is/are allowed.
- 6) ☒ Claim(s) 26-28, 31, 55, 56 and 63-65 is/are rejected.
- 7) ☒ Claim(s) 30, 40, 58 and 61 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: For example, in claim 26 the new limitations “so that at least a portion of the fastener is disposed outside of the stem” is not shown in the specification. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-28, 30, and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

For example, the new limitations “so that at least a portion of the bone anchor is disposed outside of the stem” have not been found in the specification. The Applicant’s representative cannot positively claimed the phrase “at least a portion” because nowhere in the specification or the drawings show a portion of the bone anchor inside the stem. Therefore, the Examiner suggest to the Applicant’s representative to delete the language “at least a portion”.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 55, 56, 58 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner is unclear regarding the language “so as to bias against the tubular bone anchor”. The Examiner suggests to delete the language and positively claim structure limitations that describe the above language.

Regarding claim 65, nowhere in the drawings show a threaded exterior surface on the stem. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26, 31, and 64-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Cipolletti US Patent 5,489,311.

Cipolletti discloses a condylar implant (13) comprising a bearing plate (30) having a top articular surface (31), an opposing bottom surface (35), a stem (33), means for connecting a

fastener to the stem (elements 37 and 23) mechanically engaging with the stem so that at least a portion of the fastener is disposed outside of the stem (the fastener 37 or 23 are at the outer surface of the stem, therefore, the fastener are outside of the stem). And a tubular bone anchor (20) removably encircling at least a portion of the fastener so that at least a portion of the bone anchor is disposed outside the stem (see distal end of element 24 disclosing at least a portion of the structure outside of the stem (see Fig. 4).

Claims 55, and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Gerbec et al US Patent 6,866,683.

Gerbec et al discloses a condylar implant (see Fig. 20) comprising a plate (see fig. 20) having a top surface and an opposing bottom surface (see Fig. 20), a stem (20) projecting from the bottom surface, an elongated fastener (90), a tubular bone anchor (30), a nut (91).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27, 28, 63, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cipolletti US Patent 5,489,311.

Cipolletti discloses the invention substantially as claimed. However, Cipolletti does not disclose a shaft having threaded formed thereon, a porous bone ingrowth material and a threaded

socket formed on an exterior surface of the stem so that the threaded socket does not extend through the bearing plate.

Cipolletti discloses a shaft having a plurality of ribs (see Fig. 1, element 37) for connecting a second element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ribs of the Cipolletti reference with a threaded surface in order to create a strong attachment between two structure elements.

Regarding claim 64 and the ingrowth material, the Examiner interpreted the bearing plate as elements 30 & 10. Therefore, the bottom surface of element 10 clearly discloses in Figure 3 pockets that are capable of having porous bone ingrowth material.

It would have been obvious to one having ordinary skill in the art to have porous bone ingrowth material for the purpose of promoting the growth of bone tissue below the implant.

Regarding the threaded socket, see col. 4, lines 53-57.

Regarding claim 28, see element 21 disclosing the enlarged head.

Regarding claim 63, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the attachment element of the pocket with the fastener with a press fit connection because Applicant has not disclosed that by having a press fit connection provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the threaded-ribs connection shown in the Cipolletti reference because it would perform equally as well.

Therefore, it would have been an obvious matter of design choice to modify the Cipolletti reference to obtain the invention as specified in claim 63.

Allowable Subject Matter

Claims 14, 18, 21, 23, 24, 38-40, 42, 43, 45, 47, 50, 59-62, 66 and 67 are allowed.

Claims 20 and 68 have not been examined because they belong to a cancelled claim.

Claims 30, 40, 45-47, 50, and 58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 06/05/08 have been fully considered but they are not persuasive.

For example, the examiner has given a different interpretation to claims 26-28 and 64-65 in order to overcome the new limitations entered on the above claims.

Regarding claims 55, 56 and as best understood, the Examiner believes that the Gerbec et al reference still reads on the above claims and the nut 91 in connection with the elongated fastener is capable of being bias against the tubular bone anchor.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alvin J Stewart/
Primary Examiner, Art Unit 3774

July 24, 2008.